REMARKS

Pending Claims:

Claim 11 has been amended. Claims 11-15 are pending in this application.

Examiner's 112, First Paragraph Rejection:

The Examiner rejected claims 11-15 for failing to provide evidence of the antibody deposit for antibody 7G6. The specification and claims have been amended to recite the ATCC Accession number for this antibody. Further, the specification has been amended to recite the name and address of the International Depository Authority, and a statement of the attorney of record is attached.

The Examiner further rejects claims 11-15 as containing subject matter not adequately described in the specification. Applicant's respectfully traverse this rejection.

The Applicant asserts the Examples provided in the specification provide an adequate teaching to demonstrate posession of the invention as claimed. For example, the Examiner's attention is drawn to Example 3, where Prostate, Colon, and Ovarian tissues, both normal and cancerous, are probed with the antibody 7G6. In each case, the data show a protein recognized by the antibody, whereas the cancerous tissue did not contain the recognized protien. In each Western Blot, the antibody-recognized protein is shown to have a similar pattern previously recognized in the mammary cell growth inhibitory, Mammastatin, to be due to differences in phosphorylation. The antibody bound proteins have a molecular weight of approximately 51 Kd for prostate; 50 Kd for colon; and 60 Kd for ovarian. These physical characteristics of the proteins: molecular weight; pattern of banding on a gel; binding to a specific antibody; and differential expression in normal versus cancerous tissue are definitive physical and structural

characteristics of the claimed proteins that adequately support a conclusion that these proteins are members of the same protein family. Further evidence that the proteins are the claimed growth inhibitors is found in Example 1, where each of the prostate, colon, and ovarian tissues hybridized to the labeled nucleic acid sequence encoding a fragment of the mammary cell growth inhibitor, Mammastatin.

Taken together, the data provide structural evidence of posession of the prostate, colon, and ovarian proteins as claimed. Physical characteristics including approximate molecular weight, characteristic protein banding on a sizing gel, binding to an anti-mammastatin antibody, 7G6, as well as the differential expression in normal versus cancerous cells provide ample evidence that the inventor was in posession of the invention at the time of filing; and enables a scientist in this field to use the diagnostic method as claimed. Removal of this rejection is requested.

The present claims are drawn to a method for the diagnosis of prostate, colon, or ovarian cancer. The method as claimed requires examination of a patient sample (body tissue or fluid) for the presence or amount of a protien havind defined physical characteristics: molecular weight in the range of 50-60; produced by normal cells, but not cancerous, recognized by antibody 7G6. The specification has demonstrated the presence of a protein meeting these characteristics in normal prostate, colon, and ovarian tissues and fluids, but not in cancerous tissues. Idenification of a specific amino acid sequence is neither required nor appropriate to the instant claims. Removal of this rejection is requested.

Conclusion:

Applicant asserts the claims are in condition for allowance. Early notice of such allowance is solicited.

The Examiner is invited to telephone the undersigned attorney for clarification of any of these Remarks or Amendments, or to otherwise speed prosecution of this case.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 332-5300

Date: 16 January 2004

Denise M. Kettelberger, Ph.D.
Reg. No. 33,924
Customer No. 23552

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/028,952
Applicant : Paul R. Ervin, Jr.
Filed : December 18, 2001
Title : EPITHELIAL CELL GROWTH INHIBITORS
TC/A.U. : 1642
Examiner : NICKOL, GARY B.

Docket No. : 04273.0003USW1

Customer No. : 23552

CERTIFICATE UNDER 37 CFR 1.6(d):
I hereby certify that this paper is being transmitted by facsimile to the Commissioner for Patents, U.S. Patent and Trademark Office, on January 16, 2004 at facsimile number 703.305.3014.
By: Denise M Kettelberger
Name: Denise M.Kettelberger

Honorable Commissioner of Patents
Alexandria, VA 22313-1450

STATEMENT RE. BIOLOGICAL DEPOSITS

Biological materials recited in the specification, including hybridomas and plasmids having ATCC Accession Numbers, were deposited with the American Type Culture Collection, 10801 University Blvd., Manassas, VA 20110, under the provisions of the Budapest Treaty, on the dates indicated below. All restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application. Any deposited material will be replaced if viable samples cannot be dispensed by the ATCC. Copies of the ATCC Certificates of deposit are attached.

Appl. No. 10/028,952
Statement re. Biological Deposits
Reply to Office Action of October 16, 2003

Biological Material	ATCC Accession Number	Date Deposited
pMammA	97451	2/22/96
pMammB	PTA-2091	6/15/00
pMammC	PTA-2090	6/15/00
PRT-6	PTA-2092	6/15/00
7G6	PTA-4606	8/21/02

The Examiner is invited to telephone the attorney listed below with any questions or comments, or to otherwise speed prosecution of this application.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 332-5300

Date: 16 January 2004

Denise M. Kettelberger

Denise M. Kettelberger, Ph.D.
Reg. No. 33,924
Customer No. 23552

23552
PATENT TRADEMARK OFFICE

American Type Culture Collection

12301 Parklawn Drive • Rockville, MD 20852 USA • Telephone: (301)231-5520 Telex: 898-055 ATCCNORTH • FAX: 301-770-2587

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Biotherapies, Inc.
Attn: Paul R. Ervin, Jr.
3728 Plaza Drive, Suite C
Ann Arbor, MI 48108

Deposited on Behalf of: University of Michigan

Identification Reference by Depositor: ATCC Designation

Plasmid, pMAMB 97451

The deposit was accompanied by: ___ a scientific description _ a proposed taxonomic description indicated above.

The deposit was received February 22, 1996 by this International Depository Authority and has been accepted.

AT YOUR REQUEST:

X We will not inform you of requests for the strain.
X The strain is available to the scientific public upon request as of February 22, 1996

If the culture should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace it with living culture of the same.

The strain will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the culture cited above was tested February 29, 1996. On that date, the culture was viable.

International Depository Authority: American Type Culture Collection, Rockville, Md. 20852 USA

Signature of person having authority to represent ATCC:

Barbara M. Hailey

Date: March 11, 1996

Barbara M. Hailey, Administrator, Patent Depository

cc: Denise Kettleburger

ATCC

10801 University Blvd • Manassas, VA 20110-2209 • Telephone: 703-365-2700 • FAX: 703-365-2745

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Biotherapies, Inc.
Attn: Paul Ervin, Jr., Ph.D.
5692 Plymouth Road
Ann Arbor, MI 48105

Deposited on Behalf of: Biotherapies Inc.

Identification Reference by Depositor:	**Patent Deposit Designation**
Plasmid DNA: pCDNA4/PRN2.1	PTA-2089
Plasmid DNA: pGEM3Z/pmammC	PTA-2090
Plasmid DNA: pCDNA3/pmammB	PTA-2091
Plasmid DNA: pCDNA4/PRT6	PTA-2092

The deposits were accompanied by: __ a scientific description _ a proposed taxonomic description indicated above.
The deposits were received June 15, 2000 by this International Depository Authority and have been accepted.

AT YOUR REQUEST: X We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strains.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested June 28, 2000. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:

Date: June 30, 2000

Barbara E. Coupé, Administrator, Patent Depository

cc: Denise M. Kettelberger

BP/9

ATCC

10801 University Blvd • Manassas, VA 20110-2209 • Telephone: 703-365-2700 • FAX: 703-365-2745

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3 AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Biotherapies Incorporated
Attn: Paul Ervin Jr., PhD
5692 Plymouth Road
Ann Arbor, Michigan 48105

Deposited on Behalf of: Biotherapies Incorporated

Identification Reference by Depositor:

Hybridoma: 7G6.6

Patent Deposit Designation

PTA-4606

The deposit was accompanied by: __ a scientific description __ a proposed taxonomic description indicated above.

The deposit was received August 21, 2002 **by this International Depository Authority and has been accepted.**

AT YOUR REQUEST: X **We will inform you of requests for the strain for 30 years.**

The strain will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strain, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strain.

If the culture should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace it with living culture of the same.

The strain will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the culture cited above was tested August 26, 2002. **On that date, the culture was viable.**

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:

Marie Harris

Marie Harris, Patent Specialist, ATCC Patent Depository

Date: August 29, 2002

cc: Ms. Denise Kettleberger
(Ref: Docket or Case No.: HB 10152)

BT4/9